

Polycystic Ovarian Syndrome Study

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Why is this study important?

Mood stabilizers (such as lithium or Depakote) are primary medications used to treat bipolar disorder. Therefore, potential side effects of these medications on women's reproductive health are of great importance. This research study plans to investigate the association of mood-stabilizer medications with the gynecological problem called polycystic ovarian syndrome (PCOS).

Polycystic Ovarian Syndrome is a treatable disorder that occurs in premenopausal women. Women with PCOS have irregular and infrequent menstrual cycles, excessive hair growth, and acne. On a medical evaluation (such as the type of evaluation this study offers), women with PCOS are noted to have problems with ovulation, elevated levels of male hormones, and ovaries that become enlarged and have multiple cysts. PCOS has important health consequences, including an increased risk of diabetes, infertility, and possibly, heart disease and cancer of the uterus. Evidence of a possible link between valproate (Depakote) use and PCOS has come from studies of women with epilepsy. We are conducting this important study because it is not known whether women with bipolar disorder who take Depakote are at risk for PCOS.

What does the study require?

This research study plans to enroll 300 women from participating STEP-BD (Systematic Treatment Enhancement Program for Bipolar Disorder) sites across the country. Study participants should be 18–45 year-old women who have been diagnosed with Bipolar Disorder. Participation in this study includes completion of questionnaires, one blood test, a skin examination for acne and hair growth, and an ultrasound examination of the ovaries. Women who are not enrolled in the STEP-BD research program will have a diagnostic psychiatric evaluation during their screening visit. The study visit will be scheduled during the early part of your menstrual cycle, and will also last approximately one hour. The ultrasound examination is optional, but strongly recommended.

What is the ultrasound exam, and why should I have it?

The ultrasound examination is an important part of this research study. The ultrasound will allow us to look at your ovaries and the lining of your uterus to determine if your ovaries are enlarged and if they have multiple small cysts, which is seen in women with PCOS. The ultrasound will enable us to tell if your ovaries are going through the normal changes required for the menstrual cycle.

The ultrasound can be performed in two ways: transabdominally and transvaginally. In a transvaginal ultrasound, a small probe is inserted into your vagina. It is not painful, but you may feel some pressure. The ovaries are much more clearly visualized with this method, and women are strongly encouraged to get a transvaginal ultrasound. Women who have never had sexual intercourse, however, should get a transabdominal ultrasound.

Transabdominal ultrasounds are performed by pressing a probe against your lower abdomen over a full bladder. You will be required to drink a great deal of water prior to the exam. This type of exam should be given to all women who have never been sexually active. The ovaries, however, are much harder to see clearly. If you get the transabdominal ultrasound, we may not be able to see whether your ovaries and uterus appear normal.

What are the benefits of participating?

By participating in this research study, you will find out whether you have the gynecological problem of PCOS. If you have PCOS, you can be given advice about where you can get treated. In addition, your hormone levels and ovaries will be examined free of charge. Should any abnormal results appear, you will be advised how to best treat the problem. You will receive \$40 for completing the questionnaires, blood test and skin examination. You will be given another \$40 if you have an ultrasound examination.